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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/441,140 11/16/99 SOLOMON B 27/150

001444 HM12/0629
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WASHINGTON DC 20001-5303

EXAMINER

BANSAL, G

ART UNIT	PAPER NUMBER
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1642

DATE MAILED:

06/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/44,140

Applicant(s)

Solomon

Examiner

Egtha Bansal

Group Art Unit

1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1-8-01
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-99 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-99 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

-DETAILED ACTION

Reissue Applications

1. Applicant's response of January 8, 2001 has been entered. Applicant added new claims 88-99. Accordingly, claims 1-99 are pending.

2. Applicant has submitted a certificate under 37 C.F.R. 3.73 (b) an offer to surrender the patent, and consent of assignee, which appear to be proper. Applicant's remarks on pages 3- 4 (first full sentence) is not clear. Clarification is requested.

Claims 5-99 are rejected under 35 U.S.C. 251 as being improperly broadened in a reissue application made and sworn to by the assignee and not the patentee.

In the previous office action, claims 5-87 had been rejected under 35 U.S.C. 251 as being improperly broadened in a reissue application made and sworn to by the assignee and not the patentee. Applicant's arguments in the last response has also been considered and have been answered to in the sections that follow.

3. Claims 1-99 are rejected as being based upon a defective reissue Declaration under 35 U.S.C. 251 as set forth below. See 37 CFR 1.175.

The nature of the defect(s) in the Declaration is set forth in the discussion below in this Office action. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MEP. § 1414) because of the following:

The format of the Declaration is improper. The pages present as 1 of 2, 2 of 2 and yet there is a third page that contains the explanation of the error that necessitated this reissue submission. This third page does not contain any serial number, date, inventor name, etc. that would link it to the Declaration, if it is part of the Declaration.

Further, apparently added to the end of Paper No: 2, preliminary amendment A, filed 11/16/1999, another copy of the explanation of error is attached. Again it is not signed and dated or connected in any way with any of the other papers in the file. The format is improper for consideration. The text of the Declaration is not legible due to extremely poor quality of the

copies. For instance, on the sheet which says reissue Application Declaration by the Assignee (again the quality of the copies are poor and illegible), on page 1, non-initialed changes have been made - see blue ink changes to date of Nov. 18, 1997 and whited out portions by inventor's name.

For the reasons set forth above, a new oath or declaration is required and because it is not clear if the inventor's signature is the same as the parent case, as well as the attachment to the declaration is not identified. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MEP. §§ 602.01 and 602.02.

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Applicant must file a single, complete and unaltered document in compliance with 37 CFR 1.63 and 37 CFR 1.175.

4A. In response to Applicant's argument in the last response, regarding the inventor's Declaration, it is submitted that Examiner is not arguing the matter of legibility or illegibility of Applicant's signature. The signature of the inventor in the parent 08/358,786 differs from the instant application's Declaration. (There are two pages to this Declaration with the Inventor's signature appearing on page 2).

4B. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

4C. With respect to the comment on the "attached Restriction Groups", it was an inadvertent mistake. Applicant is requested to disregard the statement as no restriction requirement was intended to be sent out.

5. The original claims in the issued Patent 5, 688, 651 (USSN 08/358,786) were drawn to a method for selecting an anti-aggregation molecule, wherein the anti-aggregation molecule is selected from a group consisting of monoclonal or recombinant antibody, an antigen binding fragment and a single chain antibody, and wherein the specificity of the anti-aggregation molecule is to a target a polypeptide which aggregates. This invention is entirely drawn to an in vitro method of assay.

The newly added claims are drawn to **different inventions** that were not claimed in the original patent. See M.P.E.P. 1412.01.

The claims in the parent application 08/358,786 had been subjected to restriction requirement. They were, as had been set forth in the parent:

Group I - claims 1-6 (original claim) drawn to a method of selecting an antiaggregation molecule.

Group II - claims 7-23 (original claims) drawn to a method of treating a protein aggregation disease by administering an expression vector encoding an anti aggregation molecule, a pharmaceutical composition and expression vectors.

Group III- claim 24 (original claim) drawn to a method of treating a protein aggregation disease by administering a monoclonal antibody.

Group I was elected for prosecution. Groups II and III were cancelled in the parent Application.

Claims 1-4 of the instant application correspond to Group I of the parent application 08/358,786, and were the elected group for prosecution.

6. Claims 5, 9-11, 15-16, 20 (which are all in part drawn to antibody), 6-8, 12-14, 17-19, 21-52, and 85 (in part drawn to antibody) are rejected under 35 U.S.C. 251 as

being an improper recapture of claimed subject matter deliberately canceled in the application for the patent upon which the present reissue is based. As stated in *Ball Corp. v. United States*, 221 USPQ 289, 295 (Fed. Cir. 1984):

The recapture rule bars the patentee from acquiring, through reissue, claims that are of the same or broader scope than those claims that were canceled from the original application.

The instant claims 5-52 and 85, corresponding in subject matter to Groups II and III of the parent application had been restricted out and cancelled in the parent application, as explained below. See M.P.E.P. 1412.02.

A. Claims 21-52, are drawn to the same subject matter as the original claims of Group II of the parent case 08/358,786, which were not elected and were cancelled during prosecution.

B. Claims 5-20, 85 are drawn to the same subject matter as the original claims of Group III of the parent case 08/358,786, which were not elected and were cancelled during prosecution.

It is noted that there are no divisionals or continuations filed from the parent application 08/358,786. Failure to file a divisional application is not considered to be an error that can be corrected by filing a re-issue application (See M.P.E.P. 1450).

7. Newly submitted claims 5 (in part) 11, 15-16, 20, 53-75, 76-79 (in part), 80-84, 85 (in part), 86-99, are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: The instant claims 5 (in part) 11, 15-16, 20, 53-75, 76-79 (in part), 80-84, 85 (in part), 86-99, are directed to methods and compositions which are directed to inventions that are independent and distinct from the invention originally claimed because the originally elected invention was drawn to a method of selecting an anti-aggregation molecule in an in vitro assay. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 5 (in part) 11, 15-16, 20, 53-75, 76-79 (in part), 80-84, 85 (in part),

86-99, are rejected under 35 U.S.C. 251 as being directed to inventions that are not directed to the same general invention in that the claims are now directed to new inventions. See M.P.E.P. 1412.01 and 1412.03. These claims are directed to inventions that do not merely enlarge the scope of the claims, but actually broaden the scope of inventions claimed in the original patent, by claiming different inventions. Therefore, these claims are improperly broadening the inventions.

8. It is noted that text is missing from pages 2, 3, 5, 1013-14, 16-17, and 18 at the top due to improper margin size. It is requested that the missing text be submitted in the form of substitute pages or a substitute specification in its entirety with proper margins. See M.P.E.P. 608.01 and 37 C.F.R. 1.52 for guidance.

9. Claims 1-4 will be considered allowable if the Declaration is amended.

10. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 4995.

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12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 28, 2001

A handwritten signature in cursive script, appearing to read "Bansal", with a horizontal line drawn underneath it.

**GEETHA P. BANSAL
PRIMARY EXAMINER**